SafeOp™ Accessory Instruments (With a Use-By Date)

INSTRUCTIONS FOR USE

Sterile and Non-Sterile

GENERAL INFORMATION:

The SafeOp Accessory Instruments include various sterile and non-sterile devices provided packaged with a use-by or expiry date. Accessories that are supplied sterile are sterilized via ethylene oxide (EO), are single use, and should be discarded after use. Accessories that are supplied non-sterile such as SafeOp™ system Surface Electrodes should NOT be sterilized and are single-use accessories which should be discarded after use.

The Arcus™ Stimulating Targeting Needle is a single use instrument used to initiate or "target" the pedicle in conjunction with other MIS instruments (e.g., k-wire or guide wire). Arcus is offered with an impaction type handle with either a diamond or bevel tip. The distal shaft and tip are made of conductive materials, so the instrument can act as a stimulation electrode.

SafeOp Accessory Instruments are surgical instruments that provide electrical stimulation to the body to locate and identify nerves in either open, minimally invasive, or percutaneous procedures. These surgical instruments are compatible with common FDA cleared neuromonitoring platforms as they are connected via a compatible clip or probe depending on the system. The neuromonitoring capability provides the surgeon with spinal nerve location, proximity, and integrity information. This information assists the surgeon during targeting, bone preparation, and placement of orthopedic implants such as intervertebral fusion devices (e.g., interbodies) and bone screws (e.g., pedicle screws).

INDICATIONS:

The *SafeOp Accessory Instruments* are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

WARNINGS/CAUTIONS/PRECAUTIONS:

1. Sterile single use instruments are disposable devices, designed for single use and should not be reused or reprocessed.
2. Reprocessing of single-use instruments may lead to instrument damage and possible improper function.
    a. Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
3. Electrocautery on a patient who is being monitored may cause interference with the neuromonitoring. Be sure to follow the electrocautery manufacturer's instruction for proper placement and connection of the return electrode to avoid shock and/or burns at the electrode sites.
4. The long-term effects of cutaneous electrodes for electrical stimulation and/or recording are unknown.
5. Use caution if electrodes are applied over areas of skin that lack normal sensation.
6. Replace self-adhesive electrodes if they no longer stick firmly to skin.
7. If replacing surface electrodes on a patient due to poor contact or incorrect positioning, carefully remove the remaining gel from the patient prior to applying the new electrodes.
8. Your patient may experience skin irritation beneath the surface electrodes applied to skin. The adhesive may irritate the skin when removed from the skin. It is a strong adhesive and should be removed from the skin with care.

9. Needle electrodes may cause bruising or bleeding in patients using blood thinners or who have blood dyscrasias. Do not move or wiggle electrodes excessively after placement.
10. Care must be taken when using stimulating instruments near vital organs, nerves, or blood vessels.
11. Incorrect handling of these instruments may render them unsuitable for their intended use, cause corrosion, dismantling, distortion, breakage, or cause injury to the patient or user. Do not use the drills and taps at high speeds.
12. All instruments are made of biocompatible materials but are not intended to be implantable. As such, in the event an instrument breaks, no fragment may remain in the patient as this could cause post-operative complications such as allergies, infection, or complications that could potentially require further intervention.
13. Alphatec distributes Rhythmlink® subdermal needle electrodes manufactured by Rhythmlink International, LLC. Subdermal Needles are for professional use only and should only be used in compliance with accepted industry standards. Rhythmlink International, LLC is not responsible for injury, infection or other damage resulting from the use or misuse of this product. Product is sterile only if packaging is unopened. When selecting a Subdermal Needle Electrode, it is important to choose the appropriate length and diameter.

RECOMMENDATIONS:

Alphatec recommends the following maximum stimulation parameters:

- Max Current: 40 mA
- Max Voltage: 380 V
- Max Pulse Width: 200 µs
- Max Frequency: 20 Hz
- Max RMS Current: 2.53 mA

PACKAGING AND STORAGE:

Inspect each package upon receipt to ensure it is intact. Examine accessories carefully prior to use for completeness such that all components are included and to confirm there is no damage. Do not use devices if package is opened, damaged, or past the use-by or expiry date. Damaged packages or products should be returned to Alphatec.

Rhythmlink subdermal needle electrodes include Single Needles: one Electrode per pouch and Paired Needles: two electrodes per pouch. Rhythmlink® needle electrodes may be stored at ambient temperatures in a clean, dry location. All sterile accessories are intended for single use only. This product should NOT be re-sterilized.

SafeOp Dual Surface Electrodes are provided in various quantities within a single pouch. Electrodes are offered with multiple pad configurations: three conductive pads per backing, two conductive pads per backing, and a single conductive pad per backing. SafeOp wet gel surface electrodes are provided non-sterile and must be stored at room temperature (10°C to 32°C or 50°F to 90°F) in a clean, dry location. This product should NOT be sterilized.

PREOPERATIVE AND INTRAOPERATIVE MANAGEMENT

General Electrode Instructions:

- Inspect the patient's skin prior to electrode application to assure that the skin is healthy, intact, clean, and dry.

- Remove the backing or needle coverings from the electrodes prior to placing on the patient.
- Anchor all electrodes with medical tape.
- For all electrodes a swab (e.g., '2x2' size) may be placed under the cable connector if it appears that cushioning is needed. Adhesive tape can be placed over the connector or cables to provide strain relief.
- A ground electrode must be placed for all recordings.
- A Rhythmlink® subdermal needle electrode may be used for current return (e.g., for a bipolar stimulating probe) which connects to the touch proof green connector.

Alphatec Spine SafeOp Surface Electrodes:
Alphatec Spine SafeOp Surface Electrodes can be identified by the silver Mylar backing with the Atec logo on the reverse side. For best results prepare the site as follows: Remove excess hair, oils, and dirt. Wash the site with warm soapy water and dry the area completely. Use light sandpaper prep to lightly scrub area and wipe with alcohol prep then let dry. Remove the Mylar backing from the electrode and place the electrode on the prepared site. To assure good contact apply pressure in the center of the electrode and move to the edges. Upon completion of the recording, remove electrode by pulling directly on the electrode. DO NOT PULL ON THE CABLE. Clean any remaining hydrogel with clean soapy water.

Rhythmlink Subdermal Needle Electrodes:
Prior to use, remove Needle sheath. Subdermal needle electrodes are typically applied after anesthesia induction has occurred. Subdermal needle electrodes should be inserted after cleansing the skin with a non-ionic disinfectant such as isopropyl alcohol. Prior to use, remove Needle sheath. When introducing Electrode into patient, do not insert up to the hub. If needle bends before, during or after insertion, do not straighten or re-insert. Discard and replace with a new electrode. This product is single-patient use only and should not be sterilized or reused. Discard electrode after use.

- Reuse of this device may cause cross contamination and has NOT been validated for multiple uses.
- Re-sterilization of this device may cause unknown malfunctions. EO re-sterilization has not been validated for this device and may contribute to excessive EO gas residuals.

COMPLAINT HANDLING/REPORTING:
All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at customerservice@atecspine.com.

For Surgical Technique Guides or additional information regarding the products, please contact your local representative or Alphatec Spine, Inc., Customer Service directly customerservice@atecspine.com.

℞only CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of Symbols and Explanations, see **atecspine.com/eifu**

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